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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/586,106      | 06/02/2000  | David A. Wright      | P-1065              | 6179             |

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT

PAPER NUMBER

1636

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                   |                               |  |
|------------------------------|-----------------------------------|-------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>09/586,106     | Applicant(s)<br>WRIGHT ET AL. |  |
|                              | Examiner<br>Konstantina Katcheves | Art Unit<br>1636              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 5-8,13,14,19,20 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-12,15-18,21-23 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1-25 are pending in the instant application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I and SEQ ID Nos:62 and 63 in Paper No. 8 is acknowledged. The traversal is on the grounds that: (1) the instant invention is drawn to nucleic acids and vectors encoding reverse transcriptases such that a relationship exists between Group I and Group II and particularly between SEQ ID Nos: 42-164; (2) that Group II which further includes SEQ ID NO:5 can be used with SEQ ID Nos: 42-165; (3) that the Groups are in the same class and subclass; and (4) that restriction is not proper because the species are claimed under a common genus. These arguments are noted, however, not found persuasive.

Applicant should note at the outset that the search of 122 sequences presents a serious search burden for the examiner particularly considering that the size of Genbank, alone, far exceeded five million entries in 1997 and has been growing exponentially since. Contrary to Applicant's assertion, the fact that these constructs are classified in the same class and subclass does not translate into the same search. Each claimed sequence must individually be compared to each entry in each of the databases available to the Examiner.

Applicant has argued that Group II further comprising SEQ ID NO:5 should be examined with Group I because that a nucleic acid sequence encoding an envelope protein can be used with the transcriptases of the sequences claimed in Group I. Whether this is in fact true or not does not address the fundamental difference between the two groups. Group I is drawn to a nucleic acid comprising a construct encoding a transcriptase encoded by SEQ ID Nos:62 or 63 while

Group II encodes a construct comprising such transcriptase and further comprising an envelope protein. These are entirely different and independent constructs such that restriction is proper. Applicant also argues that the restriction requirement as it relates to SEQ ID Nos:42-165 is in proper and should have at least been properly made as an election. Applicant's interpretation of the restriction requirement is noted however not persuasive. Each nucleic acid disclosed in even numbered sequences of SEQ ID Nos: 42-164 encode the proteins disclosed by the odd numbered sequences of SEQ ID NOS:43-165. Each sequence disclosed is unique from the other and are thus separate and patentably distinct inventions. Therefore, each such nucleotide and amino acid sequence represents an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq.

Applicant should note that the restriction requirement required that Applicant elect one (1) SEQ ID NO to be fully responsive. However, Applicant elected Group I and SEQ ID Nos:62 and 63. Although the response was not proper and the examiner was not required to search both SEQ ID Nos, Applicant has been accommodated in order to expedite prosecution. Accordingly, claims 5-8, 13, 14, 19, 20, and 24 have been withdrawn from consideration. Claims 1-4, 9-12, 15-18, 21-23 and 25 have been examined insofar as they read on elected SEQ ID Nos:62 and 63. Applicant is reminded that the claims should be amended to remove references to non-elected SEQ ID Nos.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

Claims 1-4, 9-12, 15-18, 21-23 and 25 are objected to because of the following informalities: The present claims contain references to non-elected subject matter. All such references to non-elected subject matter should be removed. Claims 1, 9 and 15 also contain inappropriate punctuation. The instant claims contain periods after steps (c) and (d). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9-12, 15-18, 21-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The present claims are broadly drawn to a nucleic acid that encodes "at least a portion of" a transcriptase comprising nucleic acid sequences of SEQ ID NO:62 or 63 including those having 85% identity to SEQ ID NO:62 or SEQ ID NO:63 and those having 95% identity to SEQ ID NO:62 or SEQ ID NO:63. The instant claims also recite limitations drawn to allelic variants of these nucleic acid sequences.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. .

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[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The instant claims read on a broad genus of nucleic acid constructs. However, neither the claims nor the specification as filed indicate what distinguishing attributes the members of the claimed genus of polypeptides share. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to the claimed nucleic acid constructs. Furthermore, the specification does not disclose where these modifications can be tolerated to maintain the activity of the transcriptase encoded by the claimed constructs. The specification fails to disclose a single representative example of a nucleic acid having 85% or 90% identity encoding a functional retroelement reverse transcriptase. The claims only require that the nucleic acid construct comprises a portion of the SEQ ID Nos: 62 or 63 have either 85% or 95% identity with the claimed sequences. Thus, the scope of the claims includes numerous structural variants because a significant number of structural differences between the genus members are permitted. Neither the specification nor the claims provide any guidance as to what specific changes should be made.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics of the members of the genus and because the genus is highly variant, the disclosed sequences alone are not sufficient to describe the claimed genus. Thus, one of skill in the art would reasonably conclude that Applicant was not in possession of claimed invention.

Claims 1-4, 9-12, 15-18, 21-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art

- 7) the predictability of the art, and
- 8) the breadth of the claims.

The present claims are broadly drawn to a nucleic acid that encodes "at least a portion of" a transcriptase comprising nucleic acid sequences of SEQ ID NO:62 or 63 including those having 85% identity to SEQ ID NO:62 or SEQ ID NO:63 and those having 95% identity to SEQ ID NO:62 or SEQ ID NO:63. The instant claims also recite limitations drawn to allelic variants of these nucleic acid sequences.

Applicant has failed to teach one of skill in the art may use a nucleic acid encoding "at least a portion of" a reverse transcriptase. Apparently, the portion of the nucleic acid need not be functional nor result in a functional reverse transcriptase base upon the breadth of the instant claims. In step (d) of claims 1, 9 and 15, it is not clear how the nucleic acid fully complementary either SEQ ID NO:62 or SEQ ID NO:63 would ever result in a functional reverse transcriptase. Moreover, the "allelic variants" recited in the instant claims do not equate into functional reverse transcriptases. The specification fails to disclose which nucleic acid sequences are functional, how to use the non-functional nucleic acid sequences, which sequences with 85% or 95% homology are active and encode functional reverse transcriptases, and how complementary nucleic acid sequences encode functional reverse transcriptases.

Thus, in view of the absence of teachings or working examples in the specification, the state of the art, and the breadth of the claims, one of skill in the art would not be able to make and use the invention of the instant claims. Applicant may obviate the instant rejection by including a functional limitation to the instant claims.



The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 9-12, 15-18, 21-23 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 9 and 15, Applicant recites nucleic acid sequences that have certain percent identity based upon the DNAsis computer program and its default parameters. This limitation renders the instant claims vague and indefinite because DNAsis and other DNA sequence comparison algorithms are subject to change depending upon the technology available. With such a limitation to a specific algorithm such as DNAsis, the inherent deficiencies in measuring identity render the metes and bounds of the claim unclear. Therefore, any limitation based upon a particular algorithm is necessarily vague and indefinite and does not clearly limit the claimed invention.

Claim 25 recites the term "*etc.*" This term is necessarily vague and indefinite because it necessarily recites elements not actually disclosed such that the scope of the instant claim is not readily ascertainable.

Steps (c) and (d) of claims 1, 9 and 15 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. The metes and bounds of this Markush group is indefinite because it is unclear if the members of this group are mutually exclusive. One acceptable form of alternative expression, which is commonly

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referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush , 1925 C.D. 126 (Comm'r Pat. 1925).


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
April 8, 2002

  
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